

REMARKS

This responds to the Office Action dated July 17, 2003. Claims 1, 3, 7 – 9, 17, and 19-20 are amended. Claims 2 and 18 are cancelled without prejudice or disclaimer. The amendments to claims 3, 7, 8 -9, and 19 – 20 are solely to change dependencies in view of cancelled claims from which they previously depended. No claims are added. As a result, claims 1, 3-17, and 19-35 are now pending in this application.

§102 Rejection of the Claims

Claims 1, 10, 11, 13 – 17, 23, 25 – 31, 33 and 35 were rejected under 35 U.S.C. § 102(b) as anticipated by Sheldon et al. (U.S. Patent No. 6,044,297). Applicant respectfully traverses.

Regarding claims 1, 10, 11, and 13 – 16, Applicant can find no disclosure in Sheldon et al. of detecting a condition correlative to hypotension, including detecting a thoracic impedance signal associated with a portion of the subject's thorax, in which the detecting the thoracic impedance signal includes detecting a component of the thoracic impedance associated with a fluid shift away from the thorax, as presently recited or incorporated in these claims. Moreover, the Examiner recognized that such claim language is absent from Sheldon et al. (*See Office Action at page 3.*) Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

Regarding claims 17, 23, and 25 – 30, Applicant can find no disclosure in Sheldon et al. of a hypotension condition detection circuit to detect a hypotension condition in a subject and to provide a hypotension detection indicator, in which the hypotension condition detection circuit includes a thoracic impedance detection circuit to receive a thoracic impedance signal from the subject, a baseline component of the thoracic impedance signal associated with a fluid shift away from the thorax corresponding to the hypotension condition. as presently recited or incorporated in these claims. Moreover, the Examiner recognized that such claim language is absent from Sheldon et al. (*See Office Action at page 3.*) Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

Regarding claims 31, 33, and 35, Applicant can find no disclosure in Sheldon et al. of a means for detecting a hypotension in a subject and providing a responsive hypotension detection indicator, as presently recited or incorporated in these claims. Applicant notes that this claim

limitation is in means-plus-function form under 35 U.S.C. § 112, paragraph 6, and must therefore be interpreted in accordance with the structures disclosed in the specification, and their equivalents. However, the disclosure describes the corresponding elements as including a hypotension detection circuit using transthoracic impedance, which Applicant cannot find in Sheldon et al. Moreover, the Examiner expressly recognized that such features are absent from Sheldon et al. (See Office Action at page 3.) M.P.E.P. § 2183 also requires the Examiner to make a *prima facie* case of equivalence under 35 U.S.C. 112, paragraph 6. However, the Office Action has not presented an explanation or a rationale as to why the disclosure of Sheldon et al. is equivalent to the corresponding elements (e.g., hypotension detection circuit using transthoracic impedance) disclosed in the specification, as is required by the M.P.E.P. § 2183. Applicant respectfully submits that Sheldon et al. does not disclose any equivalent to the corresponding elements disclosed in the specification under 35 U.S.C. 112, paragraph 6. Therefore, Sheldon et al. does not anticipate claims 31, 33, and 35. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

§103 Rejection of the Claims

Claims 2 – 9, 12, 18 – 22, 24, 32 and 34 were rejected under 35 U.S.C. § 103(a) as obvious over Sheldon et al., in view of Combs et al. (U.S. Patent No. 5,957,861). Claims 2-3 and 18 have been cancelled, thereby mooting this basis of rejection with respect to those claims. Applicant respectfully traverses with respect to the others of these claims, and with respect to claims 1 and 17, which have been amended to incorporate the limitations of claims 2-3 and 18, respectively.

The Examiner's burden of establishing a *prima facie* case of obviousness requires, among other things, that each and every one of the recited claim limitations are taught or suggested in the cited prior art reference(s) independent of the teaching in the applicant's disclosure. See *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); M.P.E.P. § 2142. However, Applicant can find no disclosure, teaching, or suggestion in Sheldon et al. and/or Combs et al. of detecting hypotension using thoracic impedance associated with a fluid shift away from the thorax, as recited or incorporated in claims 1, 4-9, 12, 17, and 19-22 and

(using the proper means-plus-function interpretation with respect to the specification) for claims 32 and 34.

Applicant would like to strongly emphasize that Combs et al. does not relate to hypotension. Instead, Combs et al. apparently pertains to discerning edema. (*See* Combs et al. at Abstract). Moreover, Combs et al. states that pulmonary edema refers to fluid accumulation in the lungs, which involves a fluid shift toward the thorax. (*See, e.g.,* Combs et al. at column 1, lines 27-36.). By contrast, the present claims refer to hypotension, as detected using thoracic impedance to detect a fluid shift away from the thorax. Similarly, the specification of the present patent application notes that hypotension refers to “low blood pressure” or “too-low intravascular fluid tension,” which is associated with a fluid shift away from the thorax. (*See* Application at page 2, lines 25-26; *see also* page 8, line 28, *see also* page 9, lines 1-16.) As explained in Combs et al, edema—in direct contrast to hypotension—involves fluid accumulation in the lungs, that is, a fluid shift toward the thorax. Therefore, Combs et al.’s discerning edema fails to disclose (and actually teaches directly away from) detecting hypotension. Therefore, because all elements of the present claims are not disclosed, taught, or suggested in Sheldon et al. and/or Combs et al, and because Combs et al. furthermore actually teaches away from the present claim language, Applicant respectfully submits that no *prima facie* case of obviousness presently exists with respect to these claims. Therefore, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612-373-6951) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743

Respectfully submitted,

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Date Oct. 15, 2003

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 15 day of October, 2003.

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